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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,953 | 06/17/2002 | Anthony Douglas Shannon | 28594/38247 | 2556 |
| 4743 | 7590 | 10/19/2005 | | |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | EXAMINER HILL, MYRON G | |
| | | | ART UNIT 1648 | PAPER NUMBER |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,953

Applicant(s)

SHANNON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 23-50 is/are pending in the application.
- 4a) Of the above claim(s) 32-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the paper filed June 17, 2005.

Claims 21-31 are under consideration in the action.

Claim Objections Withdrawn

Claims 25-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicant's arguments were persuasive and the rejection is withdrawn.

Claim Rejections Withdrawn

35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a subunit vaccine of BVDV, does not reasonably provide enablement for any subunit vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant's arguments were persuasive and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

Claims 21-24 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava (WO 99/29834, from IDS).

Applicant's arguments were persuasive and the rejection is withdrawn.

New Claim Rejections - 35 USC § 103

Claims 21, 23, 24 and 29-31 are rejected under 35 U.S.C. 103(a) as being anticipated by Srivastava (WO 99/29834, from IDS).

The claims are drawn to a method of producing an immunogenic complex comprising expressing an antigenic peptide in a non-mammalian cell, subjecting the cell stimulus that causes induction of heat shock response, and recovering the complex.

Srivastava teaches a method of making an immunogenic complex comprising HSP and heterologous antigenic peptide in insect cells (page 32, lines 18-27) and that heat shock proteins can be induced by heat shocking the cells and the complexes purified (page 34, lines 25-36).

One of ordinary skill in the art at the time of invention would have known that antigen-hsp complexes could be expressed by baculovirus in insect cells, heat shocked and the complexes recovered as taught by Srivastava with the expectation of success

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using this method to produce a complex of antigen with non-mammalian hsp in a non-mammalian cell because the elements of the method are known to work.

Thus, it would be *prima facie* obvious to make an immunogenic complex comprising a hsp and a heterologous antigenic peptide using baculovirus and heat shocking the cells to produce the complex.

Claims 21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava and Deregt *et al.* (1998 Virus Res Vol 57, pages 171-181).

The claims are drawn to a method of producing an immunogenic complex comprising a step wherein the cell has been subjected to a stimulus that causes induction of heat shock response.

Srivastava is discussed above and teaches making immunogenic complexes with HSPs in the new rejection.

Srivastava does not teach virus or BVDV as the heterologous antigenic peptide.

Deregt *et al.* teach that BVDV is a known pathogen of bovines and that the E2 region has been used as a subunit vaccine (page 172, column 1, second full paragraph).

One of ordinary skill in the art would have been motivated to use the general vaccine method of Srivastava to make other immunogenic formulations because Srivastava teaches that the made compositions give rise to immune responses.

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One of ordinary skill in the art would have been motivated to use BVDV because it is known that it is a common virus and has economic implications because of the disease it causes.

Applicant argues the Srivastava reference and that the Deregt et al. does not make an effective vaccine.

Applicant's argument has been considered and found persuasive in part.

The Srivastava rejection has been reformulated and the Deregt *et al.* argument is not persuasive because the claims are not drawn to making a vaccine but to an immunogenic complex.

Thus, it would be prima facie obvious to use the method of Srivastava with the antigen of Deregt *et al.* to make an immunogenic composition.

Claim Rejections - 35 USC § 112

Claims 21 and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the term "non-mammalian heat shock response" means and it is not clear the metes and bounds of the stimulus that causes it.

Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. The metes and bounds of what defines "derivative" and "fragment" are not clear not clear.

Applicant argues that there are different strains and hypervariable regions in flaviviruses and that breadth of claim cannot be construed as indefinite.

Applicant's arguments have been fully considered and not found persuasive.

The claims require an antigenic polypeptide as applicant points out. The hypervariable regions are known as pointed out by Applicant. The metes and bounds of antigenic peptide or polypeptide are clear. Applicant has not pointed to where the term is defined in the specification and that it is clearly limited to those explanations and the specification does not provides a clear indication of what is meant by the terms. Also, it is not clear what the derivative peptide becomes (how derived can it be and still be the desired antigen).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is requested to point out support for

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the term "non-mammalian heat shock response". The Examiner cannot locate support for the term in the specification.


Conclusion

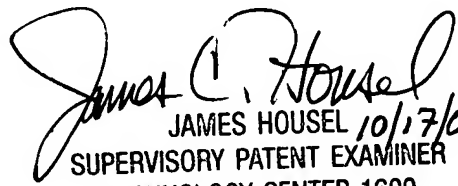
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Myron G. Hill
Patent Examiner
10 October 2005


JAMES HOUSEL 10/17/05
SUPERVISORY PATENT EXAMINER
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